510(k) Summary of Safety and Effectiveness

MAR 2 5 2010

General Provisions Trade Name: AngioDynamics, Inc. Morpheus® SMART PICC CT and Procedure Kit

Classification Name: Percutaneous, Implanted, Long-Term, Intravascular Catheters 80 LJS

Name of Predicate Devices The following predicate devices have been identified for the 6F Triple Lumen Morpheus® SMART PICC CT and Procedure Kits:

Dévice Name	510(k) Number	Concurrence Date
AngioDynamics Morpheus® CT PICC	K070615	May 04, 2007
and Procedure Kits	K060887	April 24, 2006
	K041420	July 26, 2004
	K040446	March 05, 2004
•	K031626	June 19, 2003
	K030415	April 30, 2003
Bard Access Systems, Inc. 6 Fr TL PowerPICC® Catheter	K053501	January 13, 2006

Contact Name

Jodi Lynn Frasier

Senior Regulatory Affairs Professional

Access Business Unit AngioDynamics, Inc

603 Queensbury, NY 12804 (518) 798-1215 ext 1676

Date Summary Prepared

March 01, 2010

Classification

Class II

Performance Standards

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Percutaneous, Implanted, Long-Term, Intravascular Catheters.

510(k) Summary of Safety and Effectiveness, Continued

Intended Use and Device Description

The AngioDynamics 6F Triple Lumen Morpheus® SMART PICC CT and Procedure Kit is intended for short or long term peripheral access to the central venous system for intravenous therapy, power injections of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion, or therapy use a 4 French or larger catheter. For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used. The device is available as a procedural kit with either a Stylet or a Nitinol Wire.

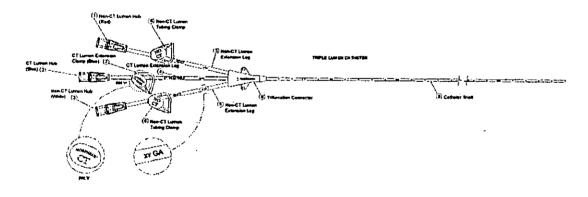
Biocompatibility

The 6F Triple Lumen Morpheus® SMART PICC CT and Procedure Kit have been tested for biocompatibility per ISO 10993. All data demonstrate this device is biocompatible for its intended use.

Summary Comparing Technological Modifications

The AngioDynamics 6F Triple Lumen Morpheus® SMART PICC CT and Procedure Kits device description is as follows:

- 6 French outside diameter, reversed tapered shaft design
- Catheter usable length is 55 cm
- Shaft inner lumen is a triple lumen design
- Catheter shaft tubing is marked with depth indicators
- The catheter has one power injectable lumen
- The product labeling warns against power injection procedures through the two small lumens, which are clearly identified as non CT.
- Three extension legs to facilitate injection through each lumen of the catheter shaft.



510(k) Summary of Safety and Effectiveness, Continued

Summary Comparing Technological Modifications (continued)

The only modifications that were made are as follows:

- Expand the existing product line to provide a 6F triple lumen catheter shaft. The existing Morpheus® product line currently provides a 6F and 7F Dual lumen catheter design, while
- The catheter shaft is a single durometer material vs. the dual durometer design of the existing product portfolio. The material is the same base material as the distal end of the currently marketed Morpheus® PICC CT and Procedure Kits, with the exception of the barium loading. The 6F triple device will have a 20% Barium loading which is the same as the proximal end of the currently marketed Morpheus® PICC CT and Procedure Kits.
- An additional extension leg has been added to facilitate injection through the third lumen of the catheter shaft. The extension leg materials are identical to those of the currently marketed dual lumen Morpheus® PICC CT and Procedure Kits.
- A natural colored luer will be utilized for the third lumen of the catheter. This luer
 has identical specifications as those used on the existing Morpheus® PICC CT and
 Procedure kits and is of the same material. The only difference is the omission of a
 colorant (red or blue) so that each lumen has a distinctly colored luer for
 identification purposes.
- Use of a silicone processing aid, for which leave trace amounts may remain on the finished device.

510(k) Summary of Safety and Effectiveness, Continued

Summary of Verification Activities

The table immediately following outlines the verification/validation activities completed on the proposed device and compares that to the predicate device.

Test	Proposed Device Acceptance Criteria	Proposed 6F Triple Catheter (K093406) T=0	Proposed 6F Triple Catheter (K093406) T=1	Predicate Device Acceptance Criteria	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=0	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626,
Tip Whip	Tip "whipping" is defined as the tip moving from left to right during an injection. Tip whipping must be less than or equal to predicate devices	Pass	Pass	Tip "whipping" is defined as the tip moving from left to right during an injection. Tip whipping must be less than or equal to predicate devices	Pass	K030415) T=1
Tip Displacement	Tip displacement is defined as the tip backing-up during an injection. Tip displacement must be less than or equal to predicate devices	Pass	Pass	Tip displacement is defined as the tip backing-up during an injection. Tip displacement must be less than or equal to predicate devices	Pass	Pass

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	,,,,,				Morpheus® CT	Morpheus® CT
		A Section			PICC and	PICC and
					Procedure Kits	Procedure Kits
		Proposed 6F	,		(K070615,	(K070615,
		Triple	, , , ,	Predicate	K060887,	K060887,
	Proposed Device	Catheter	Proposed 6F	Device	K041420,	K041420,
		1 12		! .	K040446,	K040446,
	Acceptance	(K093406)	Triple Catheter	Acceptance	K031626,	K031626,
Test	Criteria	T=0 ↓	(K093406) T=1	Criteria	K030415) T=0	K030415) T=1
CT Injection -	Flow Rate =		-	Flow Rate = 3		
Catheter Flow	5mL/sec ±			to 8mL/sec ±		
Rate	0.5mL/sec with			0.5mL/sec		
	95% confidence			(depending		
	that 95% of the			on catheter		
	population meets specification			configuration) with 95%		
	specification			confidence		
				that 95% of		
				the	:	:
				population		
				meets		
		Pass	Pass	specification	Pass	Pass
CT Injection -	CT Lumen must			CT Lumen		
CT Lumen	withstand a			must		
Integrity	minimum of 10	•		withstand a		
	injections at a			minimum of		
	minimum flow rate			10 injections		
	of 5mL/sec with a			at a minimum		
	95% confidence			flow rate of 3		
	that 80% of the			to 8mL/sec		
	population meets			(depending		
	specification			on catheter		
				configuration)		
				with a 95%		
	i			confidence		
				that 80% of the		
				population		
				meets		
		Pass	Pass	specification	Pass	Pass

Proposed Device Acceptance (K093406) T-1 (R093406) T-1 (R0	. •.			,	4 54 - 2, 3	Angio Dynamics.	'AngioDynamics
Proposed 6F. Triple Acceptance Acceptance Criteria Aspiration Minimum aspiration rate to be 3cc/min using a 10cc syringe without total collapse (all three catheter lumens) with 95% confidence that 95% of the population meets specification Gravity Flow Rate Proposed 6F. Triple Catheter (K093406) T=0 (K093406) T=1 (K093405) T=0 Minimum aspiration rate to be 3cc/min using a 10cc syringe without total collapse (all three catheter lumens) with 95% confidence that 95% of the population meets specification Procedure Kits (K070615, K060887, K041420, K041440, K041420, K041440, K031626, K031626, K031626, K030415) T=0 Minimum aspiration rate to be 3cc/min using a 10cc syringe without total collapse (all three catheter lumens) with 95% confidence that 95% of the population meets swift of the population meets swift of the population meets swift of the population meets sylve of the population meets sylve of the population meets specification Procedure Kits (K070615, K060887, K041420, K041440, K041420, K041410, K0414							
Proposed Device Acceptance (K093406) Test Criteria T=0 Triple Catheter, (K093406) T=1 Triple		1			1.		
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Aspiration Minimum aspiration rate to be 3cc/min using a 10cc syringe without total collapse (all three catheter lumens) with 95% confidence that 95% of the population meets specification Pass Pa	Test	Criteria	T=0	(K093406) T=1			
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confidence that 95% of the population meets specification Pass P					collapse (all	i	
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population meets specification Pass Pass							
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Rate flow rate to be 750 mi/hr for CT lumen and 182 ml/hr for non-CT lumens with 95% confidence that population meets specification flow rate to be 750 ml/hr for CT lumen and la2 ml/hr for non-CT lumens with population meets specification gravity flow rate to be 750 ml/hr for CT lumen and la2 ml/hr for non-CT lumens with population confidence that.95% of the population meets	Cuarita Ela	No.	Pass	Pass		Pass	Pass
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and 182 ml/hr for non-CT lumens with 95% confidence that 95% of the population meets specification meets	Rate						
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confidence that 95% of the population meets specification TOD-CT lumens with 95% confidence that 95% of the population meets							
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Pass Specification Pass Dacc		İ	Pass	Pass	specification	Pass	Pass

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					AngioDynamics	AngioDynamics
					Morpheus® CT	Morpheus® CT
					PICC and	PICC and
11.					Procedure Kits	Procedure Kits
		Proposed 6F	f de	• = .	(K070615,	(K070615,
	• •	Triple	•	Predicate	K060887,	K060887,
,	Proposed Device	Catheter	Proposed 6F	Device	K041420,	K041420,
1: 1	Acceptance	(K093406)	Triple Catheter	Acceptance	K040446,	K040446,
Test	Criteria	T=0	(K093406) T=1	Criteria	K031626,	K031626,
Stylet	Stylet withdrawal	1-0	(11033400) 1-2	Stylet	K030415) T=0	Ř030415) T≐Í
Withdrawal	force must be less			withdrawal	,	b
Testing	than 2 lbs with 95%	•		force must be	i	
	confidence that			less than 2 lbs		
	95% of the			with 95%		
	population meets			confidence		
	specification			that 95% of		
	oper		•	the		
				population		
				meets		
		Pass	Pass	specification	Pass	Pass
Wire	Guidewire		, , , , ,	Guidewire	, 433	1 0 2 3
Withdrawal	withdrawal force	İ		withdrawal		
Testing	must be less than 2	•		force must be		
, .	lbs with 95%			less than 2 lbs		
	confidence that			with 95%		•
	95% of the			confidence	i	
	population meets			that 95% of		
	specification			the		
	'			population		
				meets		
		Pass	Pass	specification	Pass	Pass
Static Burst	Catheter burst			Catheter burst		
	pressure must be			pressure must		
	greater than 150 psi			be greater	[
	with 95%			than 150 psi		
,	confidence that			with 95%		
	95% of the			confidence		ļ
	population meets			that 95% of		
	the specification			the		
				population		
				meets the		ļ
		Pass	Pass	specification	Pass	Pass

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		***			Morpheus® CT	Morpheus® CT
[, ,					PICC and	PICC and
1		1			Procedure Kits	Procedure Kits
]:.		Diameter Cr	20 (34)		(K070615,	(K070615.
		Proposed 6F		100	K060887,	K060887,
		Triple		Predicate	K000887, K041420,	1
1. 4	Proposed Device	Catheter	Proposed 6F	Device	K041420, K040446,	K041420,
·	Acceptance	(K093406)	Triple Catheter	Acceptance	K040440, K031626,	K040446, K031626,
Test	Criteria	T=0	(K093406) T=1	Criteria	K031020, K030415) T=0	K030415) T=1
Dynamic Burst	Catheter dynamic	<u> </u>		Catheter	11000415)1	1000410) 1-1
-	burst pressure must			dynamic burst		
	be greater than 300			pressure must		
	psi with 95%			be greater		
	confidence that			than 300 psi	1	
	95% of the			with 95%		
	population meets			confidence		
	specification	i		that 95% of		
				the		
				population		
		,		meets		
		Pass	Pass	specification	Pass	Pass
•			Tensile Testing	i. i	1 600	.\$ 41
Extension Leg to	Tensile strength			Tensile		
Natural Color	must be greater	l		strength must		
Hub	than 5 lbs with 95%			be greater		
	confidence that			than 5 lbs		
	99% of the			with 95%		
	population meets			confidence		
	the specification			that 99% of		
				the population		
				meets the		
		Pass	Pass	specification	Pass	Pass
Non- CT	Tensile strength			Tensile		
Extension Leg to	must be greater			strength must		
Trifurcate	than 5 lbs with 95%			be greater		
	confidence that			than 5 lbs		
	99% of the		ļ	with 95%		
	population meets			confidence		
	the specification			that 99% of		
				the population		
		5	_	meets the	_	_
		Pass	Pass	specification	Pass	Pass

			C. C.		AngioDynamics	AngioDynamics
					Morpheus® CT	Morpheus® CT
. "		5.5			PICC and	PICC and
	· ·		.4		Procedure Kits	Procedure Kits
	. ,	Proposed 6F			(K070615,	(K070615,
	1.8	Triple		Predicate	K060887,	K060887,
<i>'</i>	Proposed Device	Catheter	Proposed 6F	Device	K041420,	K041420,
	Acceptance	(K093406)	Triple Catheter	Acceptance	K040446,	K040446,
Test	Criteria	T=0	(K093406) T=1	Criteria	K031626,	K031626,
CT Extension	Tensile strength	1-0	(1000400) 101	Tensile	K030415) T=0	K030415) T=1
Leg to Trifurcate	must be greater	•		strength must		
8 /	than 5 lbs with 95%			be greater		
	confidence that			than 5 lbs		
	99% of the			with 95%		
	population meets	,		confidence		
	the specification			that 99% of		
	in openineation					
				the population meets the		
		Pass	Pass	specification	Pass	Pass
Shaft to	Tensile strength		1 033	Tensile	F 433	Fd33
Trifurcate	must be greater			strength must		
	than 5 lbs with 95%			be greater		
	confidence that	'		than 5 lbs	i	
	99% of the			with 95%		
	population meets			confidence		
	the specification			that 99% of		
				the		
				population		
		i		meets the		,
		Pass	Pass	specification	Pass	Pass
Catheter Shaft	Tensile strength			Tensile	1 033	F 433
	must be greater			strength must	ĺ	
	than 5 lbs with 95%		ı	be greater		
	confidence that			than 5 lbs		
	99% of the			with 95%		
	population meets		•	confidence		
	the specification			that 99% of		
1	· ·•		İ	the		
		1	ļ	population		
		J		meets the		
		Pass	Pass	specification	Pass	Pass

Test	Proposed Device Acceptance Criteria	Proposed 6F Triple Catheter (K093406) T=0	Proposed 6F Triple Catheter (K093406) T=1	Predicate Device Acceptance Criteria	AngioDynamics Morpheus® CT PICC and Procedure Kits (K070615, K060887, K041420, K040446, K031626, K030415) T=0	
		CVP	Pressure Monitorin	ıg .		
Pressure Monitoring	No difference observed between SVS and catheter in mean pressure, systolic pressure and diastolic pressure as compared to predicate devices	Pass		No difference obsetween SVS and in mean pressure, pressure and diaste pressure as compa predicate devices	catheter systolic olic	Pass
Natural Frequency	The natural frequency must be equal to or greater than the predicate device	Pass		The natural freque must be equal to o than the predicate	ncy r greater	Pass

Summary of Substantial Equivalence The 6F Triple Lumen Morpheus® SMART PICC CT and Procedure Kit have been tested and compared to the predicate device. All data gathered demonstrate this device is substantially equivalent. No new issues of safety or efficacy have been raised.

Additional Information

Material Change

In addition to the previously submitted information, AngioDynamics would like to identify an additional change for the device submitted for the pending 510(k) K093406. A silicone material is used as a processing aid which may leave trace amounts on the device. As a result, this MDX silicone should be identified as a material present and included in the 510(k). All testing previously conducted were on units built with this processing aid and as a result representative of the finished device for which we seek marketing clearance. This was an omission in the original submission.

Biocompatibility Data

MDX Silicone, manufactured by Dow is a commonly used medical grade material. Extensive biocompatibility testing has previously been conducted. The following page provides written authorization to allow the Food & Drug Administration to access these data for purpose of this submission review.







Food and Drug Administration 10903 New Hampshire Avenue Document Control Room --WO66-G609 Silver Spring. MD 20993-0002

MAR 2 5 2010

AngioDynamics, Incorporated Ms. Jodi Lynn Frasier Senior Regulatory Affairs Professional Access Business Unit 603 Queensbury Avenue Queensbury, New York 12804

Re: K093406

Trade/Device Name: Morpheus® SMART PICC CT and Procedure Kit

Regulation Number: 21 CFR 880.5970

Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter

Regulatory Class: II Product Code: LJS Dated: March 1, 2010 Received: March 2, 2010

Dear Ms. Frasier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm 115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Section 6

Statement of Indications For Use

INDICATIONS FOR USE

510(k) Application:	Special 510K Application
	,
Device Name:	AngioDynamics, Inc. Morpheus® SMART PICC CT and Procedure

Indications for Use:

The AngioDynamics, Inc. Morpheus[®] SMART PICC CT and Procedure Kit is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injections of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion, or therapy use a 4 French or larger catheter. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

Prescription Use X	OR	Over-the-Counter Use
(Per 21 CFR 801.109)		

Please do not write below this line - continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Of#

division of Anesthesiology, General Hospital

efection Control, Dental Devices

10(k) Number: <u>K093406</u>

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